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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,838	07/13/2001	Avi Ashkenazi	10466/72	5331
35489	7590	12/29/2003	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP			ROMEO, DAVID S	
275 MIDDLEFIELD ROAD			ART UNIT	
MENLO PARK, CO 94025-3506			PAPER NUMBER	
			1647	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,838

Applicant(s)

ASHKENAZI ET AL.

Examiner

David S Romeo

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-47 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1203.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1647

DETAILED ACTION

The amendment filed 12/04/2003 has been entered. Claims 44-47, 49-51 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Priority

The present claims are directed to or encompass a polypeptide comprising the amino acid sequence of SEQ ID NO: 114. Based on the priority statement filed August 26, 2002 and an inspection of the patent applications, the examiner has concluded that the claimed subject matter is supported by the disclosure in application serial no. PCT/US00/04414, filed February 22, 2000 but is not supported by any of the others because the claimed subject matter is not supported in the manner provided by 35 U.S.C. 112, first paragraph in any of the earlier filed applications.

Applicant relies on the gene amplification assay (Example 92) for support of patentable utility, which was first disclosed in PCT/US98/18824 filed September 10, 1998, priority to which is claimed in the present application. Applicant's arguments have been fully considered but they are not persuasive. The present claims are directed to or encompass the PRO317 polypeptide (SEQ ID NO: 114). The data disclosed in example 92 and table 8 of the present application discloses gene amplification of DNA encoding the PRO317 polypeptide. The specification asserts at page 222, full paragraph 2, that amplification is associated with overexpression of the gene product, indicating that the polypeptides are useful targets for therapeutic intervention in certain cancers such as colon, lung, breast and other cancers and diagnostic determination of the presence of those cancers. However, no information is provided in the gene amplification data

Art Unit: 1647

regarding the level of expression, activity, or role in cancer of the PRO317 polypeptide. Further, WISP-2 genomic DNA was amplified in colon cancer cell lines and in human colon tumors, but RNA expression was reduced (2- to >30-fold) in 79% of the tumors. See Pennica (U), Abstract. This evidence indicates that DNA amplification is not always associated with overexpression of the gene product. Consequently, the asserted diagnostic utility of the PRO317 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use, and the increased copy number of PRO317 DNA does not provide a readily apparent use for the PRO317 polypeptide, for which there is no information regarding the level of expression, activity, or role in cancer. The gene amplification data disclosed in example 92 and table 8 of the present application, which was first disclosed in PCT/US98/18824, filed September 10, 1998, does not satisfy the utility requirement of 35 U.S.C. § 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. § 112, first paragraph, for the polypeptide.

Claim Rejections - 35 USC § 102

Claims 44-47, 49-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (N, PTO-892 200309).

Applicant argues that the effective filing date of this application is September 10, 1998 and since Ruben is dated after the effective filing date of the present application, it is not prior art under 102(a) and this rejection should be withdrawn. Applicant's arguments have been fully considered but they are not persuasive. As discussed above, the gene amplification data disclosed in example 92 and table 8 of the present application, which was first disclosed in

Art Unit: 1647

PCT/US98/18824, filed September 10, 1998, does not satisfy the utility requirement of 35 U.S.C. § 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. § 112, first paragraph, for the polypeptide. The claimed subject matter is supported by the disclosure in application serial no. PCT/US00/04414, filed February 22, 2000. Accordingly, the effective filing date claimed subject matter is February 22, 2000.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 44, 47, 50, 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 44, 47, 50, 51 are indefinite because they recite the term “amino acid sequence of the secreted polypeptide.” Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of “amino acid sequence of the secreted polypeptide” an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Information Disclosure Statement

37 CFR 1.98(b) requires that each item of information in an IDS be identified properly. The information disclosure statement filed 12/04/2003 indicates, implies, or suggest that copies of the listed documents have been supplied by Applicant, when in fact they have not. To the extent that the information disclosure statement filed 12/04/2003 is intended to provide on a

Art Unit: 1647

separate list in compliance with 37 CFR 1.98(a)(1) the "Other Art" in the information disclosure statement filed March 14, 2002 in order to have the references printed on a resulting patent, then the information disclosure statement filed 12/04/2003 does not properly identify each item of information in the IDS filed March 14, 2002. Note that the IDS filed March 14, 2002 was initialed by the examiner and a copy was provided to Applicant in the Office action mailed 09/09/2003. The "Other Art" in the IDS filed March 14, 2002 will be printed on a resulting patent exactly as it was provided, i.e., "Blast Results A1-A16, GenBank" and "Blast Results, B1-B9, Dayhoff." If this will work for Applicant, then it will work for the Office. The examiner regrets any confusion he may have caused.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1647

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

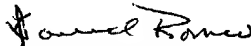
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
DECEMBER 22, 2003